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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,607	04/16/2004	Kevin John Slater	4730.00015	8055
22907 7590 01/18/2007 BANNER & WITCOFF			EXAMINER	
1001 G STREI	ET N W		SHEN, BIN	
SUITE 1100 WASHINGTO	ON, DC 20001		ART UNIT	PAPER NUMBER
	•		1657	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		01/18/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

•	Application No.	Applicant(s)				
Office Action Summany	10/825,607	SLATER ET AL.				
Office Action Summary	Examiner	Art Unit				
	Bin Shen	1657				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status		•				
1) Responsive to communication(s) filed on 13 No	ovember 2006.					
2a) ☐ This action is <b>FINAL</b> . 2b) ☑ This	action is non-final.					
3) Since this application is in condition for allowan	3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims	•					
4)⊠ Claim(s) <u>1-34 and 44-48</u> is/are pending in the a	application.					
4a) Of the above claim(s) is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.	•					
6)⊠ Claim(s) <u>1-34 and 44-48</u> is/are rejected.						
7) Claim(s) is/are objected to.	•					
8) Claim(s) are subject to restriction and/or	election requirement.					
Application Papers						
9)☐ The specification is objected to by the Examiner	·.	•				
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119						
12)⊠ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a)⊠ All b)□ Some * c)□ None of:						
1. Certified copies of the priority documents have been received.						
2. Certified copies of the priority documents have been received in Application No						
3. Copies of the certified copies of the priority documents have been received in this National Stage						
application from the International Bureau (PCT Rule 17.2(a)).						
* See the attached detailed Office action for a list of the certified copies not received.						
Attachment(s)		•				
1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413)						
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) Information Disclosure Statement(s) (PTO/SB/08)  Paper No(s)/Mail Date  Notice of Informal Patent Application						
Paper No(s)/Mail Date 6) Other:						

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#### DETAILED ACTION

The IDS received 8/26/2004, 10/13/2004, the preliminary amendment received 8/26/2004 have been entered.

#### Election

Applicant's election of Group I, claims 1-34, 44-48 in the reply filed on 11/13/2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Applicant's cancellation of claims 35-43 in the reply fled on 11/13/2006 is also acknowledged.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-34, 44-48 are presented for examination on the merits.

## Specification

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: Mycoplasma detecting methods and materials.

## Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 1-34, 44-48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1-3 and all occurrences, it is not clear what (A) and (B) mean? It is not clear that all (A)s indicate the measurement of control sample and all (B)s indicate the measurement of test sample.

In claim 8, lines 2 and 4, it is not clear what "obtention" means.

## Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-34, 44-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Kahane et al. (FEMS Microbiology Letters 1978;3:143-145) in view of Ito et al. (Analytical Sciences 2003;19:105-109).

Kahane teaches a mycoplasma acetate kinase activity assay comprises detecting/measuring the appearance/disappearance of one or more of the substrates/products of the reactions as claimed in claim 3 after osmotically lysis (page 143, Materials and Methods and Results and Discussion, 1<sup>st</sup> and 2<sup>nd</sup> paragraph),

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and that acetate kinase is present in mycoplasma (page 143 end of  $1^{st}$  paragraph and page 145, lines 1-7).

Kahane does not teach the detection of mycoplasma in cell culture and the assay reaction is a bioluminescent reaction

Ito teaches a bioluminescent measurement of acetate kinase (Title and abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Kahane by using Ito's bioluminescent method because both methods teach acetate kinase assays. One would have been motivated to make the modification because Kahane et al. specifically described the acetate kinase assay and Ito et al. teach the advantages of the bioluminescent method, and would reasonably have expected success in view of Ito's teaching that no interference in the measurement of the acetate kinase and with good sensitivity when using their bioluminescent method (page 107, 1st full paragraph). The choice of detecting mycoplasma in cell culture using enzyme activity ratio of testing sample over control sample, the adjustment of particular conventional working conditions (e.g., use of detergent, incubation time period for the reaction, choice of cell lines) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan having the cited reference before him/her.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was

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made, as evidenced by the references, especially in the absence of evidence to the contrary.

### Conclusion

No claim is allowed.

Certain papers related to this application may be submitted to Art Unit 1657 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is 571-273-8300. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the

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problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Any inquiry concerning rejections or objections in this communication or earlier communications from the examiner should be directed to Bin Shen, Ph.D., whose telephone number is (571) 272-9040. The examiner can normally be reached on Monday through Friday, from about 9:00 AM to about 5:30 PM. A phone message left at this number will be responded to as soon as possible (i.e., shortly after the examiner returns to her office).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached at (571) 272-0925.

Recours

RALPH GITOMER PRIMARY EXAMINER GROUP 1200

B Shen

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